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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,525	04/06/2000	Ralf M. Luche	200125.408	7819

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/27/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/544,525

Applicant(s)

Luche

Examiner

Rebecca Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 9, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45, 46, and 50-55 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45, 46, and 50-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on Oct 9, 2002 is: a) ☐ approved b) ☒ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-44 and 47-49 have been canceled. Claims 45, 46 and newly presented claims 50-55 are still at issue and are present for examination.

Applicants' arguments filed on 10-9-02, paper No. 16, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The amendment filed 2/1/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation by reference of provisional application 60/142,338. While applicants response indicates that the recitation of the provisional application in the original transmittal contained a typographical error, there is no support in any of the original application papers for the corrected serial number (both references to this provisional recited the wrong serial number) and thus incorporation by reference of the subject matter of this application is new matter.

Applicants argue that the incorporation by reference of application 60/142,338 is not new matter as the correct serial

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number of the provisional application is recited in the declaration of the inventors. This is not persuasive because the declaration was not filed with the original application but for months later as a response to a notice of missing parts. While the rules allow a signed declaration to be filed subsequent to the filing date, the disclosure of the invention must be complete as of the filing date. This was not the case as nothing filed with the original application papers supports the amended serial number. Applicants citation of 37 CFR 1.76(d)(1) which states that when information cited in an application data sheet is inconsistent with information in the declaration of the inventors, the information in the last filed document will govern is no relevant as the instant situation is not an inconsistency between an application data sheet and the declaration. Furthermore, it is not the claim to priority that is at issue but whether the incorporation by reference of the subject matter of the provisional application is new matter.

The amendment filed 10-9-02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: new Figures 1-3 and the new sequence listing. While all of the

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information in these amendments is found in provisional application 60/142,338 which applicants incorporate by reference, this incorporation by reference is new matter as discussed above and thus the instant amendments are new matter as well.

Applicant is required to cancel the new matter in the reply to this Office Action.

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 10-9-02 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(a)(6) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of the sequences of Figures 1-3.

The disclosure is objected to because of the following:

The description of the polynucleotide of SEQ ID NO:1 on pages 12 and 44 is confusing. On page 12, lines 10-15 the specification states "The DSP-3 active site VHCLAGVSRS (SEQ ID NO:3) is encoded by nucleotide bases located at positions 258 through 285 of SEQ ID NO:1". However positions 258 through 285 of SEQ ID NO:1 are the sequence ccattctcaaaacctgacaagacatttca, which is not sufficiently lengthy to encode 10 amino acids and which would encode the sequence PSQNLTRHF. Similarly, page 44

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describes the active site domain as beginning at position 258 of SEQ ID NO:1.

Appropriate correction is required.

Claims 45, 46, and 50-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The polypeptide sequence of SEQ ID NO:2 as now recited was not supported by the application as filed.

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for substrate trapping mutations of amino acids 57 and 88 of SEQ ID NO:2, does not reasonably provide enablement for any substrate trapping mutant of any dual specificity phosphatase having 75% identity to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants argue that the rejection under 35 U.S.C. §112, first paragraph is not proper because the specification teaches

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the complete nucleotide and amino acid sequences of the dual specificity phosphatase of SEQ ID NO:2, methods for determining the percent identity of variant sequences to SEQ ID NO:2, and methods for testing for enzymatic activity, and K_m of binding substrate, and methods for producing variants of a disclosed sequence are within the skill of the ordinary artisan. This is not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., variants which remain the binding affinity to substrate but have substantially reduced catalytic activity) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute **undue** experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been

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provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified to reduce phosphatase activity without effecting substrate binding activity; (B) the general tolerance of dual specificity phosphatases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues of SEQ ID NO:2 with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Such guidance is essential in the case of the instantly claimed variants as the number of residues which could be altered such as to retain substrate binding affinity while losing catalytic activity is likely to be extremely limited as the vast majority of alterations would be expected to either reduce both catalytic activity and substrate binding affinity or not to effect either property.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty
Primary Examiner
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